



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 12 2005

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

This is in response to your letter of July 11, 2005, concerning off-label use of ultrasound equipment for entertainment purposes. As your letter notes, the Food and Drug Administration (FDA or the Agency) has posted information on its website warning consumers against the use of ultrasound imaging to produce "keepsake" videos of developing fetuses. Your letter states that "there is no scientific evidence to support the FDA's claims" that ultrasound administered to a fetus outside a healthcare setting can cause harm, and you cite a study published in *The Lancet* in December 2004 to support your statement.

The Lancet study involved only sonograms administered by trained personnel in a medical setting. The major concern expressed by FDA on its website is that sonograms used to produce keepsake images may be administered using substandard equipment in an uncontrolled environment by untrained personnel. Under these circumstances, both the dosage and the duration of exposure may exceed safe amounts, and the fetus can be exposed to an unknown level of risk without any medical benefit. An additional concern expressed in the article on FDA's website is that, in the absence of trained professionals to interpret the images and provide counseling if needed, an apparently normal ultrasound image may dissuade parents from proper prenatal care, while an apparently abnormal image may cause distress and unnecessary additional procedures. In sum, the Agency agrees with the American College of Obstetrics and Gynecologists that pregnant women should avoid "casual" exposure to ultrasound.

Nonetheless, after reviewing petitions requesting that the Agency allow expanded use of handheld Doppler fetoscopes, the Agency is planning to hold a public meeting to discuss scientific data about the exposure to ultrasound energy. Although the meeting will not focus on the use of ultrasound equipment for keepsake images, we believe the discussion will be relevant to the scientific and public health considerations related to "entertainment" uses of sonograms.

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We believe that the statement on our website concerning keepsake videos provides valuable information to consumers. We also believe that the suggestion in your letter that the Agency should send new notifications retracting or mitigating previous warnings to marketers and promoters of keepsake videos and commit to not sending new letters would not be in the interest of public health.

Your letter also raises concerns about claims that condoms are effective in preventing the transmission of sexually transmitted diseases. As discussed in our letter of October 19, 2005, FDA has developed guidance related to these concerns. See Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex, issued on November 14, 2005. Please refer to this letter for additional discussion of this issue.

Thank you for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, reading "Patrick Ronan". The signature is written in a cursive, flowing style with a large initial "P".

Patrick Ronan
Associate Commissioner
for Legislation